

### **REMARKS**

The present amendment is in response to the Advisory Action mailed August 3, 2010, and supplements the previous Amendment And Reply Under 37 CFR §1.116 dated July 1, 2010 in response to the Final Office Action mailed April 1, 2010. The present amendment has been made based on the claims filed in the Amendment dated July 1, 2010, which was entered as indicated by the Examiner in the Advisory Action. Applicants respectfully request that the Examiner consider the present amendment and the following remarks as addressing the Advisory Action of August 3, 2010 and the remaining rejection set forth in the Final Office Action of April 1, 2010.

After entry of this amendment, claims 1-23 are pending. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. Claims 1 and 10 find further support in the specification, for example, at page 23, lines 40-42, page 28, lines 15-34, and page 29, lines 4-11. Claim 3 finds further support in the specification, for example, at page 28, lines 15-23. No new matter has been added.

Upon allowance of the generic claims or the claims directed to the elected species, Applicants respectfully request rejoinder of the non-elected species. 37 CFR § 1.141; MPEP § 809.02(a).

### **Claim Rejections – 35 U.S.C. § 112**

Applicants note initially that the Examiner's comments provided in the Advisory Action dated August 3, 2010 explaining why Applicants' request for reconsideration did not place the application in condition for allowance are primarily related to the enablement rejection. Applicants accordingly interprets that the Amendment dated July 1, 2010 at least overcame the written description rejection. The following remarks thus address only the rejection to claims 1-23 for allegedly lacking an enabling disclosure.

Without acquiescing to the merits of the Examiner's arguments, and solely for expediting prosecution, the claims have been amended without prejudice or disclaimer to recite the claimed subject matter with more specificity. As amended, claims 1 and 10 further define the NADPH oxidase, or functional equivalents thereof, by its particular sequence (i.e. SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 or 22). Thus, Applicants believe that the present amendment clarifies the Examiner's concerns that the claims encompass sequences comprising sense, antisense or

dsRNA of “any” NADPH oxidase coding sequence or functional equivalents, or sequences having 50% homology, to “non-exemplified” sequences. Advisory Action at page 2.

Moreover, Applicants respectfully submit that, as discussed in great detail in the Response dated July 1, 2010, the Schiene reference cited by the Examiner does not support the Examiner’s alleged unpredictability of the art concerning using sense or antisense technology to reduce endogenous gene expression. Rather, this reference supports enablement and show that down-regulation of gene expression using antisense technology was predictable as of, at the latest, the year of 2000, even if the gene of interest is encoded by a multigene family.

Additionally, as already discussed in great detail in the Response dated December 15, 2009, the specification provides detailed guidance, including working examples, as to how to make and use the claimed subject matter. The methodologies described in the specification are applicable not only to the full-length of SEQ ID NO: 1 as exemplified, but also any other sequences encoding NADPH oxidases as recited in the present claims for which the reduction of protein quantity, activity or function is desired. Moreover, methodologies in using sense or antisense of a sequence in reducing quantity, activity or function of the encoded protein are within the knowledge of one skilled in the art as evidenced by Schiene. Thus, although some testing and screening would be required when different methodology is used and/or different NADPH oxidase genes or parts thereof are used, such testing and screening would not be extensive and is routine in nature, and thus, not undue. On these facts, an analysis under *In re Wands* supports enablement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (routine screening of hybridomas was not “undue experimentation;” the involved experimentation can be considerable, so long as “routine”).

In view of the present amendment and further in view of the Amendment dated July 1, 2010, for the reasons already of record and for the above additional reasons, Applicants respectfully submit that the art and the specification provide ample guidance and predictability for the present claims. Accordingly, reconsideration and withdrawal of the enablement rejection is respectfully requested.

### **CONCLUSION**

In view of the above remarks and further in view of the above amendments, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a Request for Continued Examination and a petition for a two-month extension of time to and including September 1, 2010 to respond to the Office Action mailed April 1, 2010 with the required fee authorization. No further fee is believed due. However, if any additional fee is due, the Director is hereby authorized to charge our Deposit Account No. 03-2775, under Order No. 12810-00067-US from which the undersigned is authorized to draw.

Respectfully submitted,

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